Complete Summary

GUIDELINE TITLE

Use of galactogogues in initiating or augmenting maternal milk supply.

BIBLIOGRAPHIC SOURCE(S)

Academy of Breastfeeding Medicine. Use of galactogogues in initiating or augmenting maternal milk supply. New Rochelle (NY): Academy of Breastfeeding Medicine; 2004 Jul 30. 5 p. [39 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis **RECOMMENDATIONS** EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES** IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Maternal milk production

GUIDELINE CATEGORY

Evaluation Management Treatment

DISCLAIMER

CLINICAL SPECIALTY

Family Practice Nutrition

Obstetrics and Gynecology Pediatrics

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Dietitians Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To facilitate optimal breastfeeding
- To provide recommendations on the use of galactogogues in initiating or augmenting maternal milk supply

TARGET POPULATION

- Women who are adoptive nursing
- Women who need assistance with initiation, maintenance, or augmentation of maternal milk production

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

- 1. Assessing patient for indications for galactogogues (adoptive nursing, relactation, increasing declining milk supply)
- 2. Screening for contraindications
- 3. Evaluation of current maternal milk supply and effectiveness of milk transfer

Management/Treatment

- 1. Informing patient regarding the efficacy, safety, and timing of use of galactogogues
- 2. Follow-up of mother and infant
- 3. Galactogogue use

MAJOR OUTCOMES CONSIDERED

- Maternal milk supply
- Adverse events associated with treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An initial search of relevant published articles written in English in the past 20 years in the fields of medicine, psychiatry, psychology, and basic biological science is undertaken for a particular topic. Once the articles are gathered, the papers are evaluated for scientific accuracy and significance.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- I Evidence obtained from at least one properly randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports; or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

An expert panel is identified and appointed to develop a draft protocol using evidence based methodology. An annotated bibliography (literature review), including salient gaps in the literature, are submitted by the expert panel to the Protocol Committee.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Draft protocol is peer reviewed by individuals outside of lead author/expert panel, including specific review for international applicability. Protocol Committee's subgroup of international experts recommends appropriate international reviewers. Chair (co-chairs) institutes and facilitates process. Reviews submitted to committee Chair (co-chairs).

Draft protocol is submitted to The Academy of Breastfeeding Medicine (ABM) Board for review and approval. Comments for revision will be accepted for three weeks following submission. Chair (co-chairs) and protocol author(s) amends protocol as needed.

Following all revisions, protocol has final review by original author(s) to make final suggestions and ascertain whether to maintain lead authorship.

Final protocol is submitted to the Board of Directors of ABM for approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Indications for Galactogogues

Common indications for galactogogues are adoptive nursing (induction of lactation in a woman who was not pregnant with the current child), relactation (reestablishing milk supply after weaning), and increasing a faltering milk supply because of maternal or infant illness or separation. Mothers who are not directly breastfeeding but are expressing milk by hand or with a pump often experience a decline in milk production after several weeks. One of the most common

indications for galactogogues is to augment a declining milk supply in mothers of preterm or ill infants in the neonatal intensive care unit.

Procedure

- 1. Before using any substance to try to increase milk supply, a full evaluation of current maternal milk supply and effectiveness of milk transfer is imperative. Attention must be directed to the evaluation and augmentation of frequency and thoroughness of milk removal. This can be accomplished through increased frequency and duration of breastfeeding (if the infant has been shown to be effective at emptying the breasts) or pumping. A full-size, automatic cycling breast pump, capable of draining both breasts ("hospital grade") at the same time is recommended, if available. Problems such as inappropriate timing and duration of feedings, inappropriate supplementation, mother-infant separation, ineffective latch, and inadequate milk transfer should be corrected.
- 2. Women should be informed of any data (or lack thereof) regarding the efficacy, safety, and timing of use of galactogogues. With the exception of adoptive nursing, where galactogogues are started *before* the birth of the baby, there is no research to suggest that starting galactogogues within the first week postpartum is efficacious.
- Mothers should be screened for contraindications to the chosen medication or substance and informed as to possible side effects.
 Although a lactation consultant may recommend the medication or herb, it is the physician's responsibility to prescribe medications and follow the mother and infant.
- 4. The physician who prescribes the medication is obligated to follow, or to ensure appropriate follow-up, of both mother and infant regarding milk supply and any side effects. In practice, many times it is the nurse practitioner, pediatrician, or neonatologist who is asked to prescribe a galactogogue and not the obstetrician-gynecologist. As is commonly found when dealing with lactation, family physicians are ideally situated to manage this issue.
- 5. Although short-term use (1 to 3 weeks) has been evaluated for some of these substances, long-term use has not been studied. Anecdotal reports suggest no increase in side effects with the most commonly used medications (metoclopramide, domperidone, fenugreek), but long term effects on both mother and infant are unknown.

Specific Galactogogues

Many medications, foods, and herbal therapies have been recommended as galactogogues (see the section titled "Specific Galactogogues" in the original guideline document for information on metoclopramide, domperidone, sulpiride, chlorpromazine, human growth hormones, thyrotrophin-releasing hormone, and herbal/natural galactogogues). The medications used often exert their effects through antagonism of dopamine receptors, resulting in increased prolactin. In many cases, the mechanism(s) of action are unknown.

Conclusions

Of the substances used to induce, maintain, or augment milk production, domperidone and metoclopramide appear to be the most clinically useful. Prior to the use of any galactogogue, evaluation and correction of any modifiable factors such as frequency and thoroughness of breast emptying should be addressed. Medication should never replace evaluation and counseling on modifiable factors or reassurance when appropriate. As with any medication given to lactating women, close follow-up of both mother and baby is essential.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

The recommendations were based primarily on a comprehensive review of the existing literature. In cases where the literature does not appear conclusive, recommendations were based on the consensus opinion of the group of experts.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of galactogogues for initiating or augmenting maternal milk supply

POTENTIAL HARMS

Side effects of medications

CONTRAINDICATIONS

CONTRAINDICATIONS

- Metoclopramide should not be used if patients have epilepsy or are on antiseizure medications, have a history of significant depression or are on antidepressant drugs, have a pheochromocytoma or uncontrolled hypertension, have intestinal bleeding or obstruction, or have a known allergy or prior reaction to metoclopramide.
- Domperidone is contraindicated in patients with known sensitivity to the drug and in situations in which gastrointestinal stimulation might be dangerous (e.g., gastrointestinal hemorrhage, mechanical obstruction, or perforation).

QUALIFYING STATEMENTS

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A central goal of the Academy of Breastfeeding Medicine is the development of clinical protocols for managing common medical problems that may impact breastfeeding success. These protocols serve only as guidelines for the care of breastfeeding mothers and infants and do not delineate an exclusive course of treatment or serve as standards of medical care. Variations in treatment may be appropriate according to the needs of an individual patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

Academy of Breastfeeding Medicine - Professional Association

SOURCE(S) OF FUNDING

Academy of Breastfeeding Medicine

A grant from the Maternal and Child Health Bureau, US Department of Health and Human Services

GUIDELINE COMMITTEE

Academy of Breastfeeding Medicine Protocol Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Caroline J. Chantry MD, FABM, Co-Chairperson; Cynthia R. Howard MD, MPH, FABM, Co-Chairperson; *Anne Montgomery, MD, FABM; *Nancy Wight MD, FABM

* Lead author(s)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

None to report

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Academy</u> of Breastfeeding Medicine Web site.

Print copies: Available from the Academy of Breastfeeding Medicine, 140 Huguenot Street, 3rd floor, New Rochelle, New York 10801.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Procedure for protocol development and approval. Academy of Breastfeeding Medicine. 2007 Mar. 2 p.

Print copies: Available from the Academy of Breastfeeding Medicine, 140 Huguenot Street, 3rd floor, New Rochelle, New York 10801.

A German translation of the original guideline document is available from the Academy of Breastfeeding Medicine Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on November 1, 2007. The information was verified by the guideline developer on December 2, 2008.

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Date Modified: 12/15/2008

